K123785

510(k) Summary

JUN 07 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's name:	Diazyme Laboratories
Submitter's address:	12889 Gregg Court Poway, CA 92064 USA
Name of Contact Person:	Dr. Abhijit Datta Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 Phone: 858-455-4762 Fax: 858-455-3701
Date the Summary was Prepared:	June 4, 2013
Name of the Device	Diazyme Myoglobin Assay Diazyme Myoglobin Calibrator Set Diazyme Myoglobin Control Set
Trade Name:	Diazyme Myoglobin Assay Diazyme Myoglobin Calibrator Set Diazyme Myoglobin Control Set
Common/Usual Name	Diazyme Myoglobin Assay
Device Classification Name	Myoglobin Test System
Product code:	DDR (Myoglobin, Antigen, Antiserum, Control) JIT – Calibrator, Secondary JJX – Single (specified) Analyte Controls (Assayed and Unassayed)
Panel:	Immunology (82)
Submission Type	510k
Regulation Number	21CFR 866.5680
Device Class	Class II

Predicate Device:	Roche Tina-Quant Myoglobin Gen. 2 Test System and C.f.a.s. (Calibrators for automated systems) Myoglobin (K061683) Myoglobin Control Set (K973358)
Manufacturing Address	Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 USA
Establishment Registration	2032900

DESCRIPTION OF THE DEVICE

Clinical Significance

Myoglobin is a ~17kDa oxygen-binding protein whose concentration is elevated in response to a muscle injury. Characterized by x-ray crystallography in the 1950s, myoglobin has developed into an important marker for the diagnosis of a recent cardiac event. After a cardiac event or muscle injury occurs, its concentration rises and can be detected *in vitro* approximately 2 hours after the onset of symptoms and its measurement aids in the diagnosis of ST segment elevated myocardial infarction, which can ultimately lead to cardiac arrest. High concentrations of myoglobin also indicate extensive muscle damage (rhabodmyolysis) and can cause renal failure as high levels of the marker are toxic to the kidneys. The rapid increase in the concentration of myoglobin after muscular trauma makes it an important diagnostic indicator of cardiac stress and muscle damage, and provides early detection of necrosis in cardiac and skeletal muscle.

Assay Principle

The Diazyme Myoglobin Assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between myoglobin in a sample and anti-myoglobin antibodies which have been sensitized to latex particles, agglutination occurs. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of myoglobin in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.

Indications for Use:

The Diazyme Myoglobin Assay is for the quantitative determination of myoglobin in human serum and plasma. Measurement of myoglobin is used as an aid in the diagnosis of acute myocardial infarction. For *in vitro* diagnostic use only.

The Diazyme Myoglobin Calibrator Set is intended for use in the calibration of the Diazyme Myoglobin Assay. For *in vitro* diagnostic use only.

The Diazyme Myoglobin Control Set is intended for use as quality controls for the Diazyme Myoglobin Assay. For *in vitro* diagnostic use only.

Table 1 Summary of Assay Kit Components

Roche Tina-Quant Myoglobin Gen. 2, C.f.a.s. Myoglobin (k061683), and Myoglobin Control Set (k973358)	Diazyme Myoglobin Assay
Reagent 1 buffer solution, ready to use Reagent 2 Suspension of anti-human myoglobin coated latex particles, ready to use Calibrators Ready to use liquid calibrators containing myoglobin	Reagent 1 100 mM Tris buffer solution with 0.09% sodium azide, ready to use. Reagent 2 Suspension of latex particles (< 0.5%) coated with goat anti-human myoglobin with 0.09% sodium azide, ready to use. Calibrators Liquid stable calibrators prepared from human serum, purified human myoglobin, and 0.09% sodium azide.
Calibrator set	Calibrator set
3 x 1.0 mL One-Level Calibrator	1 x 1.0 mL Calibrator 1 1 x 1.0 mL Calibrator 2 1 x 1.0 mL Calibrator 3 1 x 1.0 mL Calibrator 4 1 x 1.0 mL Calibrator 5
Control Set serum based	Control Set serum based
1 x 3.0mL Control 1 1 x 3.0mL Control 2	1 x 1.0mL Control 1 1 x 1.0mL Control 2

PERFORMANCE TESTING SUMMARIES

Method Comparison

Human plasma samples were tested with the Diazyme Myoglobin Assay and the obtained results were compared to the predicate method. A total of 66 samples (ranging from 16.9 to 615.9 ng/mL of myoglobin) were tested in both assays. The above described accuracy study showed that the Diazyme Myoglobin Assay results correlated well with predicate method with a correlation coefficient of $R^2 = 0.9855$ with a slope of 0.9526 and -4.2228 y-intercept.

	Plasma Samples
n	66
Slope	0.9526
Intercept	-4.2228
Correlation R^2	0.9855

Precision

The precision of the Diazyme Myoglobin Assay was evaluated according to Clinical and Laboratory Standards Institute EP5-A guideline. In the study, three levels of serum based controls containing approximately 66, 170, and 335 ng/mL of myoglobin, respectively, and three serum sample containing approximately 35, 150, and 400 ng/mL, of myoglobin, respectively, were tested with 2 runs per day in duplicates over 20 working days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following table:

Within-Run Precision

	Control Level 1	Control Level 2	Control Level 3	Serum Level 1	Serum Level 2	Serum Level 3
N	80	80	80	80	80	80
Mean	65.97	172.8	337.0	37.78	148.6	414.3
SD	2.45	6.69	11.9	1.77	3.53	19.7
CV%	3.71%	3.87%	3.54%	4.69%	2.37%	4.80%

Total Precision

	Control Level 1	Control Level 2	Control Level 3	Serum Level 1	Serum Level 2	Serum Level 3
N	80	80	80	80	80	80
Mean	65.97	172.8	337.0	37.78	148.6	414.3
SD	3.37	7.37	14.9	1.97	5.32	21.8
CV%	5.10%	4.30%	4.40%	5.20%	3.58%	5.3%

Conclusion: For the three levels of myoglobin control and three levels of serum specimens, 20-day reproducibility data showed that the within-run precision was from 2.37% to 4.80% and total precision was from 3.58% to 5.3%. These results meet the acceptance criteria.

Linearity

A linearity set was prepared by mixing a low serum based sample of myoglobin containing 11 ng/mL and a high serum based sample of myoglobin containing 625 ng/mL, according to CLSI EP6-A. The assay was linear from 13.2 to 615.9 ng/mL.

Interference

The following substances normally present in the blood produced less than 10% deviation when tested at levels equal to the concentrations listed below:

Interferent	Concentration
Triglyceride	1000 mg/dL
Intralipid	125 mg/dL
Ascorbic Acid	176 mg/dL
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	1000 mg/dL
Rheumatoid Factor	100 IU/mL
Heparin	1.5 IU/mL
N-acetylcysteine	11.04 mM
Acetylsalicylic Acid	2.78 mM
Ampicillin	152 µM
Carbamazepine	0.13 mM
Na2-Cefoxitin	1549 µM
Ibuprofen	2425 µM
Ciclosporin	0.125 µM
Levodopa	30.4 mM
Methyldopa	71 µM
Metronidazole	701 µM
Rifampicin	78.1 µM
Theophylline	222 µM
Phenylbutazone	650 µM
Valproic Acid, Sodium Salt	3.5 mM

The assay has no intralipid interference below 125 mg/dL. Specimens from patients undergoing Intralipid therapy may have interference with the Myoglobin Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Diazyme Laboratories
C/O Abhijit Datta, Ph.D.
12889 Gregg Court
POWAY CA 92064

Re: K123785
Trade/Device Name: Diazyme Myoglobin Assay
Diazyme Myoglobin Calibrator Set
Diazyme Myoglobin Control Set
Regulation Number: 21 CFR 866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: II
Product Code: DDR, JIT, JJX
Dated: April 26, 2013
Received: April 30, 2013

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph. D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k123785

Device Name: Diazyme Myoglobin Assay, Diazyme Myoglobin Calibrator Set, Diazyme Myoglobin Control Set

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The Diazyme Myoglobin Control Set is intended for use as quality controls for the Diazyme Myoglobin Assay. For *in vitro* diagnostic use only.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123785